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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,865	06/13/2007	Gary Moore	DEP5178	7275
27777	7590	05/12/2009	EXAMINER	
PHILIP S. JOHNSON			WAGGLE, JR, LARRY E	
JOHNSON & JOHNSON				
ONE JOHNSON & JOHNSON PLAZA			ART UNIT	PAPER NUMBER
NEW BRUNSWICK, NJ 08933-7003			3775	
			MAIL DATE	DELIVERY MODE
			05/12/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/572,865	MOORE ET AL.	
	Examiner	Art Unit	
	Larry E. Waggle, Jr	3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 13 June 2007.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-15 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-15 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 03/21/2006 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>03/21/2006, 04/15/2009 and 04/16/2009</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, “the clamp” and “the actuator” must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Abstract

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to **150 words**. It is important that the abstract not exceed **150 words** in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Specification

The disclosure is objected to because of the following informalities.

On page 2, paragraph 4, line 2, the term "finalised" should read "finalized."

On page 9, paragraph 3, line 2, the term "sleeve" should be referenced as "16" where "14" is reserved for the "drill guide."

On page 10, paragraph 1, line 2, the term "leg" should be referenced as "8" where "6" is reserved for the "frame."

Appropriate correction is required.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the internal wall" in line 10, "the frame clamping surfaces" in line 12, and "the drill guide clamping surfaces" in line 13. There is insufficient antecedent basis for these limitations in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

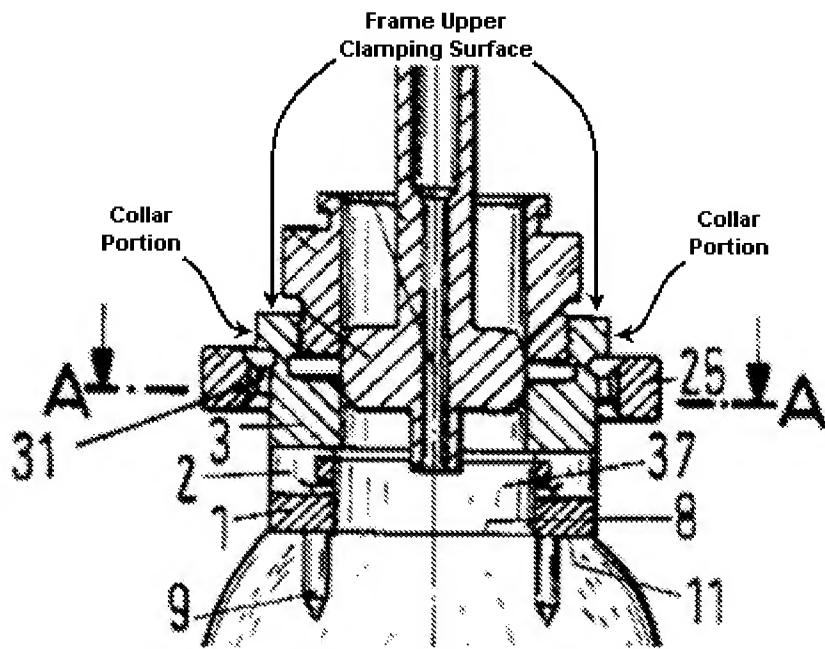
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 8-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Marchione et al. (US Patent 6595999).

Marchione et al. disclose a drill guide assembly comprising a drill guide (6) that includes a sleeve and a bulb (7) at one end of the sleeve (Figure 5), a frame fastenable (via 9) to a bone that includes a housing (3) which defines a recess (32) in which the drill guide bulb can be received with the drill guide sleeve extending out of the recess in a direction away from the bone, so that the angular orientation (α , Figure 5) of the drill guide sleeve relative to the housing can be adjusted by movement of the bulb within the recess (column 2, lines 37-41), a clamp (5) comprising a lower pair of clamping surfaces provided by the drill guide bulb and the internal wall of the recess (5, 7 and 32 in Figure 10) respectively facing generally towards the patient's bone, an upper pair of clamping

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surfaces on the drill guide and on a hollow collar portion of the housing respectively facing generally away from the patient's bone and being spaced apart from the bulb along the drill guide sleeve (see annotated Figure below), arranged so that the drill guide can be locked against angular adjustment by engagement between the frame clamping surfaces and the drill guide clamping surfaces of each of the lower and upper pairs; an actuator (29); and an alignment stylus (13) connected to the drill guide to move with the drill guide relative to the frame including a first limb that is directed towards the bone, to facilitate assessment of the alignment of the drill guide sleeve relative to anatomical features of the bone, wherein the stylus can be moved rotatably around the drill guide sleeve, the stylus can be moved around the drill guide sleeve while the clamp is engaged to prevent angular movement of the drill guide relative to the frame, and wherein the stylus includes a second limb extending from the first limb in a direction generally towards the axis of the assembly (Figure 8 and column 5, lines 25-60), and the frame provides a platform (top of 2, displacement element in Figure 9) that defines a plane that is spaced apart from the bone and an axis of the assembly (along 14) that extends perpendicular (column 5, lines 13-19) to the said plane, and wherein the drill guide is mounted on the platform so that it can be translated relative to the frame generally in the plane of the platform which includes a lock (25), and wherein the clamp and the lock can be engaged and disengaged independently of one another (column 4, lines 11-57).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marchione et al. (US Patent 6595999) in view of Reddy (US Patent 3627334).

Marchione et al. disclose the claimed invention except for one of the upper clamping surfaces being provided by a washer, and the actuator comprising a threaded nut. Reddy teaches a deformable washer (10) provided between two surfaces (31 and 32) wherein one surface (31) is an actuator (30, i.e. threaded nut) that acts on the washer to urge it against the other surface (32) (Figures 1-3 and column 1, lines 50 - column 2, line 5). It would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the invention of Marchione et al. with the deformable washer provided between two surfaces wherein one surface is an actuator that acts on the washer to urge it against the other surface in view of Reddy in order to provide a secure connection between the actuator and the upper surface to prevent the angular rotation of the drill guide.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marchione et al. (US Patent 6595999).

Marchione et al. disclose the claimed invention except for the ratio of the distance between the upper and lower clamping surfaces when the drill guide is clamped against the angular adjustment to the transverse dimension of the bulb, measured perpendicular to the axis of the drill guide sleeve being at least 1.3. It would have been obvious to one having ordinary skill in the art at the time the invention was

made to construct the invention of Marchione et al. with the ratio of the distance between the upper and lower clamping surfaces when the drill guide is clamped against the angular adjustment to the transverse dimension of the bulb, measured perpendicular to the axis of the drill guide sleeve being at least 1.3 in order to more efficiently secure and lock the drill guide from angular movement, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marchione et al. (US Patent 6595999) in view of Ashton et al. (US Publication 2006/0271058).

Marchione et al. disclose the claimed invention except for the length of at least one of the first and second limbs of the stylus being adjustable. Ashton et al. teach a first limb of a stylus (54) being adjustable (Figure 1 and page 2, paragraph 0024). It would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the invention of Marchione et al. with the adjustable first limb of the stylus in view of Reddy in order to account for the anatomy of the patient to correctly align the drill guide.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marchione et al. (US Patent 6595999) in view of Cook et al. (US Patent 6258097).

Marchione et al. disclose the claimed invention except for the frame having three legs by which it can be fitted on to a bone. Cook et al. teach a frame (12) with three

legs (32, 34 and 36) (Figure 2 and column 4, lines 43-60). It would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the invention of Marchione et al. with the frame having three legs in view of Cook et al. in order to properly center the frame on the femoral head.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry E. Waggle, Jr whose telephone number is 571-270-7110. The examiner can normally be reached on Monday through Thursday, 6:30am to 5pm, EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas C. Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Larry E Waggle, Jr/
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art
Unit 3775